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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,901	09/27/2001	Mark S. Roby	2788	3223

7590 04/19/2004

Chief Patent Counsel
United States Surgical
Division of Tyco Healthcare Group LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER
MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,901	ROBY ET AL.	
	Examiner	Art Unit	
	Jennifer K Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *16-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claim16-29 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

2. The objection to the disclosure has been withdrawn based on Applicant's amendments.

Claim Rejections - 35 USC § 103

3. Claims 1, 2, 5-7, and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelkey (5,911,711).

Examiner maintains the rejection.

4. Claims 3-4, 8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelkey in view of Mathisen et al. (5,456,948).

Examiner maintains the rejection.

Response to Arguments

5. Applicant's arguments filed 2/04 have been fully considered but they are not persuasive.

Applicant argues that Pelkey's materials are applied in multiple coatings.

Examiner notes that she has relied upon Pelkey's teachings in col. 3, lines 8-20 to provide the mixture required by Applicant. The "comprising" language of Applicant's claims does not exclude the use of a reference containing additional steps.

Applicant argues that even though one of the coating materials has a viscosity of 12,500, that there is no evidence that the viscosity of the "coating mixture" will be greater than 10,000.

Examiner disagrees. Examiner maintains the inherency rejection of this particular limitation. Applicant requires a "polydialkylsiloxane having a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000". Examiner maintains that since Applicant later requires the use of, specifically, polydimethylsiloxane in a dependent claim and that Pelkey teaches the use of the same, that this compound inherently has a molecular weight necessary to provide the desired viscosity. Clearly, a viscosity of 12,500 of a first component of a mixture has the *ability* to provide a coating mixture with a viscosity of 10,000 or more, based on the selection of the other mixture components. Most importantly, the mixture of Applicant requires polydimethylsiloxane and a siliconization material. The siliconization material of Pelkey (MDX 4-4159) and the polydialkylsiloxane of Pelkey (polydimethysiloxane) are

the same as those claimed by Applicant and as outlined by Applicant in his instant specification (p. 5 and p. 7). Therefore, the mixture of Pelkey would have the same properties as Applicant's.

Applicant argues that Pelkey teaches hypodermic needles, not surgical needles and that there is a difference between their uses.

Examiner notes that the limitation for a surgical needle is merely the intended use of the product. The eventual use of the needle is not germane to the issue of patentability. Additionally, Examiner maintains that the needles of Pelkey *could* very well be used during the course of surgery and both types of needles would benefit from a coating that decreases the penetration or drag force of insertion. Merely because the needles of Pelkey *may* not be required to remain lubricious for multiple passages through the skin/tissue, they would inherently be capable of doing so because the same types of coatings are supplied to the same types of substrate materials.

Applicant argues that the two-step curing operation and related process parameters of his invention, as outlined by dependent claims, is not suggested by Pelkey.

Examiner notes, as is taught in the previous office action, that Pelkey teaches coating the mixture onto the needles under ambient conditions, uprighting them, and then storing them for a time sufficient to achieve a partial cure. Because storing occurs after ambient coating, it is immediately envisioned by one of ordinary skill in the art that ambient conditions would persist while storing in the upright state to allow the partial

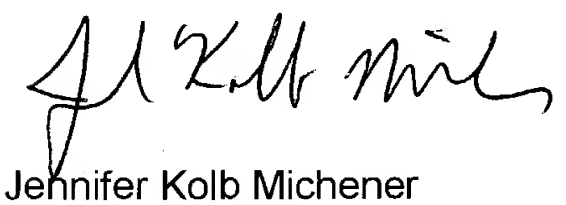
cure to occur. Without a teaching to the contrary, such as is the case in the second stage of curing, in which an oven is used, one of ordinary skill in the art, upon review of the reference as a whole, would have envisioned the partial cure to occur at the ambient conditions discussed in col. 3, line 22. Because ambient conditions lie within the range of temperature, humidity, etc. claimed by Applicant, the reference meets said limitations. Then, Pelkey teaches, to achieve a full cure oven heating is used in which temperatures above 100 C may be used so long as the needle does not contain thermoplastic parts, which Applicant's does not. Therefore, this heating temperature overlaps that of Applicant as well, as outlined in the previous office action. While the time frames for the ambient partial cure and heated full cure are not specifically disclosed by Pelkey Examiner maintains that selection of a time for curing would have been obvious to one of ordinary skill in the art based on the chemicals being cured and the temperature at which curing is conducted. Because the chemicals to be cured are the same in Pelkey as those required by Applicant and the temperatures overlap, selection of the time necessary to achieve a cure would have been within the skill of an ordinary artisan. Therefore Examiner maintains Pelkey teaches a two-step curing method involving a first-step of storing for a partial cure and a second step of oven curing, as required by Applicant.

Applicant argues that Mathisen fails to teach the deficiencies of Pelkey, said deficiencies being noted above.

Examiner notes that Mathisen was not cited to teach a 2-step curing operation or a method of coating needles, but merely to provide a teaching for the use of hexane as a suitable solvent for polydialkylsiloxane.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
April 15, 2004